K020474

JUL 2 3 2002

510(K) Summary

Submitter
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Contact
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Date Jan. 31, 2002

Trade Name
Makrite Type N-95 Healthcare Particulate Respirator and Surgical Mask Model 910-N95

Common Name:
Healthcare Particulate Respirator and Surgical Mask

Classification
Device Class - Class II
CFR Section – 21 CFR 878.4040

Substantial Equivalency:
The Makrite Model 910-N95 Heathcare Particulate Respirator and Surgical Mask is found to be substantially equivalent to the Gerson Isolair APR Type N95 Mask Model 2735 (510(K)K960778). Both products have been tested and approved by NIOSH as N-95 respirators.

USE

Description:

The Makrite Type N95 Healthcare Particulate Respirator and Surgical Mask Model 910-N95 is constructed from a white nonwoven material used in the inner and outer shell. The polypropylene melt blown filter media is layered between the inner and outer shell. The headband is made of rubber stapled to the mask. The inside nosepiece utilizes a closed cell foam and the outside nosepiece which conforms to the nose is made of aluminum.

The Makrite Type N95 Healthcare Respirator and Surgical Mask Model 910-N95 is approved by NIOSH as per 42 CFR 84. The certification number assigned is TC-84A-3323 for a type N95 Particulate Respirator. The Type N95 must meet the prescribed test criteria which specifies the use of 0.3 micron diameter challenge and requiring a 95% efficiency. This mask is resistant to synthetic blood as per ASTMF1862-00 Standard Test Method for Resistance of Medical Face Mask to Penetration by Synthetic Blood, conducted by Nelson Laboratories. Breathing resistance was tested as per NIOSH 30 CFR11 section 11.140-9.

Intended Use:

The Makrite Type N95 Healthcare Particulate Respirator and Surgical Mask Model 910-95 is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

This device also meets CDC Guidelines for TB Exposure Control.

Limitations:

This product does not eliminate the wearer from any risk of contracting any type of disease or infection. The mask should be changed immediately if contaminated with blood or body fluids.

Comparison of Predicate Device

The outside cover stock color of the preciously cleared device is white. The Makrite Model 910-N95 Healthcare Particulate Respirator and Surgical Mask Model is also white. The headband color of the cleared device is green and the Makrite Model 910-N95 is yellow.

The Makrite Model 910-N95 Healthcare Particulate Respirator and Surgical Mask incorporates a highly efficient filer media and is 95% efficient against a .3 micron particulate which was scientifically established as the most penetrating particle size. The legally marketed Gerson device previously cleared 510 (k) K960778 is manufactured from similar materials.

Performance Tests:

This product was tested and certified by NIOSH as an approved N95 respirator. It meets all the requirements prescribed in 42 CFR 84 and is assigned TC-84A-3323.

Tests Performed		Laboratory
1.	Department of Health and Human Services 42CFR 84 Type N95 Requirements	NIOSH
2.	Resistance of Liquid (Synthetic Blood Penetration Resistance) ASTMF 1862-00	Nelson Laboratories
3.	Breathing Resistance 42CFR84	NIOSH
4.	Filtration Efficiency NIOSH 42 CFR 11	NIOSH
5.	Irritation: Primary Skin FHSA Skin Sensitization	Nelson Laboratories

Conclusion:

Since the basic construction is used in the cleared device as in the new device and approved by NIOSH, the Makrite 910-95 Healthcare Particulate Respirator and Surgical Mask is substantially equivalent to the Gerson Model 2735 Healthcare and Particulate Respirator and Surgical Mask.

Safety/Effectiveness

The device has a filtration equivalent to the previously cleared Gerson Model 2735 Surgical Mask Respirator. It is NIOSH approved and meets the CDC guidelines for TB Exposure Control.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2002

Makrite Industries, Incorporated
C/O Mr. Joseph Zdrok
Joseph Z. Zdrok & Associates
24 Tower Street
Webster, Massachusetts 01570

Re: K020474
Trade/Device Name: Makrite Model 910-N95 Healthcare Particulate Respirator and Surgical Mask
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: May 28, 2002
Received: May 31, 2002

Dear Mr. Zdrok:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020474

Device Name: Makrite Model 910-N95 Healthcare Particulate Respirator and Surgical Mask

Indications For Use:

The Makrite Model 910-N95 Healthcare Particulate Respirator and Surgical Mask is a no fiberglass, fluid resistant single-use mask intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids and particulate material. This device also meets CDC Guidelines for TB Exposure Control.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020474